K120343
p 1/3

Welch Allyn

FEB 2 4 2012

510(k) Summary

[As described in 21 CFR 807.92]

Submitted by:
Welch Allyn Inc.
4341 State Street Road
Skaneateles Falls, NY 13153-0220

Contact Person:
Kevin Crossen
Director, Regulatory Affairs
Phone: (315) 685-2609
Fax: (315) 685-2532
E-mail: kevin.crossen@welchallyn.com

Date Prepared:
February 07, 2012

Trade Name:
Connex® Workstation

Common Name:
Central Station

Classification Name:
Monitor, Physiological, Patient (Without Arrhythmia Detection or Alarms)
Product Code – MWI

Classification Reference:
Class II, 21 CFR 870.2300

Predicate Device:
Acuity Central Station, Model 020XXXXX (Note: XXXXX-Various Config.)
Welch Allyn, Inc.
510(k) Number K052160

Description of the Device:

Connex Workstation is a Windows-based product that provides clinicians with a means to remotely monitor the health of several patients simultaneously. The workstation receives patient vital signs and alarm data from patient monitors over a network, then displays the data and sounds audio alarms, acting as a secondary alarm system.

Specific patient populations are determined by the requirements of the devices gathering the patient data.

In the Connex Workstation, there are two possible sources of patient data, namely:

a. Continuous monitoring devices that are attached to the patient, or

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b. Episodic measurements taken from devices that may or may not be constantly connected to the patient.

Devices providing the patient data may transfer the data electronically to the hospital network for communication with the Connex Workstation via methods such as USB, wired Ethernet, or wireless communications. The Connex Workstation is wired to the network via Ethernet.

The Connex CS system can be deployed as either a standalone central station or as a server-based deployment where one or more central stations are connected to a Connex server.

Additionally, a kiosk option may be installed on personal computers (PCs) that are running Windows 7, 64 bit, which allows the user to upload episodic data through a USB port to the Server, via the network.

Intended Use:

The Connex® Workstation is intended to be used by clinicians for the central monitoring of neonatal, pediatric, and adult patients in health care facilities. In addition to the central monitoring of patient data and alarms, the Connex software can include optional modules to provide extended recording of patient data, including full disclosure.

Technological Characteristics:

The subject device has the same technological characteristics and indications for use as the predicate device. The hardware and software functionality of the Connex Workstation remain the same as the cleared device except as described below. The Connex Workstation includes a subset of Acuity functionality. The Connex Workstation still receives continuous patient vital signs data and alarm data from patient monitors, but does not analyze data as Acuity does (i.e., Acuity performs arrhythmia monitoring and ST analysis and generates alarms based on these calculations). The Connex Workstation interfaces with the newest Welch Allyn patient monitors, rather than the older models that work with Acuity and can also receive episodic data from spot check devices, while Acuity only receives continuous data from patient monitors.

Non-Clinical Tests:

Verification and validation were conducted to ensure expected performance of the Connex Workstation.

The Connex Workstation was tested to evaluate its safety and effectiveness based on the following standards:

- IEC 60601-1-1:Ed. 2: 2000 - Medical electrical equipment – General Requirements for Safety – Collateral Standard: Safety Requirements for Medical Electrical Systems

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- IEC 60601-1-4: Consolidated Ed. 1.1: 2000 - General Requirement for Safety: Collateral Standard: Programmable Electrical Medical Systems
- IEC 60601-1-8: Ed. 1: 2003 - General requirements for safety - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (with A1:2006)
- IEC 60601-2-49: Ed. 1:2001 – Medical Electrical Equipment – Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment.
- IEC 60950-1: Ed. 2:2005 – Information technology equipment – Safety – Part 1: General requirements (with A1:2009)
- IEC 62304: Ed. 1:2006 – Medical Device Software – Software Life-Cycle Processes
- ISO 14971: Ed. 2: 2007 - Medical devices - Application of risk management to medical devices

Clinical Performance Data:
No clinical studies were utilized for the purpose of obtaining safety or effectiveness data.

Conclusion:
Based on the information presented in this 510(k) premarket notification, Welch Allyn's Connex® Workstation is considered substantially equivalent to (as safe, as effective and performs as well as) the currently marketed device cited in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB 2 4 2012

Welch Allyn, Inc.
c/o Mr. Kevin Crossen
Director Regulatory Affairs
4341 State Street Road
P.O. Box 220
Skaneateles Falls, NY 13153-0220

Re: K120343
Trade/Device Name: Connex® Workstation
Regulatory Number: 21 CFR 870.2300
Regulation Name: Physiological Patient Monitor (without arrhythmia detection or alarms)
Regulatory Class: II (two)
Product Code: MWI
Dated: February 1, 2012
Received: February 3, 2012

Dear Mr. Crossen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120343

Indications for Use

510(k) Number (if known): K 120343

Device Name: Connex® Workstation

Indications for Use:

The Connex Workstation is intended to be used by clinicians for the central monitoring of neonatal, pediatric, and adult patients in health care facilities.

In addition to the central monitoring of patient data and alarms, the Connex software can include optional modules to provide extended recording of patient data, including full disclosure.

Prescription Use (Part 21 CFR 801 Subpart D) x AND/OR Over-The-Counter Use (21 CFR 801 Subpart C) _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120343